

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION AT DAYTON

TONIA MCCORMICK,

Plaintiff,

Case No. 3:20-cv-132

vs.

CALDERA MEDICAL, INC., *et al.*,

District Judge Michael J. Newman

Defendants.

ORDER (1) GRANTING DEFENDANT ETHICON, INC.’S MOTION TO DISMISS (DOC. 22); (2) DISMISSING PLAINTIFF’S CLAIMS AGAINST DEFENDANT CALDERA MEDICAL, INC.’S FOR FAILURE TO PROSECUTE; (3) DENYING AS MOOT DEFENDANT CALDERA’S MOTION TO DISMISS (DOC. 20); (4) DENYING PLAINTIFF’S MOTION FOR LEAVE TO FILE A THIRD AMENDED COMPLAINT (DOC. 29); (5) ORDERING THE CLERK TO ENTER JUDGMENT ACCORDINGLY; AND (6) TERMINATING THIS CASE ON THE COURT’S DOCKET.

This civil case is before the Court on three motions: (1) Defendant Caldera Medical, Inc.’s (“Caldera”) motion to dismiss brought pursuant to Fed. R. Civ. P. 12(b)(1) & (6) (doc. 20); (2) Defendant Ethicon, Inc.’s (“Ethicon”) motion to dismiss brought pursuant to Rule 12(b)(6) (doc. 22); and (3) Plaintiff’s motion for leave to file a third amended complaint (doc. 29). Plaintiff filed a memorandum in opposition to Ethicon’s motion to dismiss (doc. 25), and Ethicon filed a reply (doc. 30). Plaintiff neither responded to Caldera’s motion to dismiss nor the Court’s Order requiring her to show cause as to why her claims against Caldera should not be dismissed. Doc. 27. Caldera and Ethicon both opposed Plaintiff’s motion for leave to file a third amended complaint. Docs. 31, 32. Plaintiff did not file a reply, and the time for doing so has expired. The Court will address each motion in turn.

I.

Caldera and Ethicon are medical device manufacturers. Doc. 10 at PageID 64. Caldera manufactured a transvaginal mesh (“TVM”) product named Caldera Vertessa Lite (“Vertessa Lite”) designed to correct uterine or vaginal vault prolapse. Doc. 20-3 at PageID 185. Uterine prolapse occurs when the pelvic floor muscles stretch, weaken, and can no longer support the uterus. Doc. 20 at PageID 133. Vaginal vault prolapse is a condition in which the upper portion of the vagina loses its normal shape and sags or drops down into the vaginal canal or outside the vagina. *Id.*

Ethicon manufactured Gynecare TVT mesh (“TVT”), which is intended to correct stress urinary incontinence. *Id.* Stress urinary incontinence is the unintentional loss of urine caused by physical movement or pressure placed on the bladder. *Id.* Both Vertessa Lite and TVT are surgically implanted. *Id.*

Plaintiff, through counsel, filed a complaint against Caldera and Ethicon on April 9, 2020 (doc. 1) and amended her complaint on August 14, 2020 (doc. 10). On October 8, 2020, Caldera moved to dismiss Plaintiff’s amended complaint pursuant to Rule 12(b)(1) and (6), arguing that Plaintiff’s claims are barred by the nationwide settlement covering Vertessa Lite. Doc. 20 at PageID 131.¹ Plaintiff failed to file an opposition in response to Caldera’s motion within twenty-

¹ Vertessa Lite was the subject of a multi-district litigation centered in the United States District Court for the Central District of California, No. 2:15-cv-393, and a parallel joint coordinated proceeding in California state court, JCCP No. 4733. Doc. 15-20 at PageID 561. The cases consolidated 2,710 claims brought by at least 602 plaintiffs alleging Caldera’s TVM products, including Vertessa Lite, caused them personal injury. Doc. 20-3 at PageID 182. On January 31, 2017, the Honorable Stephen V. Wilson, United States District Judge for the Central District of California, approved a settlement covering all individuals who “have asserted, are asserting, or shall have asserted” claims against Caldera for TVM-related injuries “for which a proof of a claim could have been filed by” May 2, 2016. Doc. 20-3 at PageID 188–89; doc. 20-7 at PageID 315; doc. 20-15 at PageID 561. Though, as explained below, the Court does not reach the merits of Caldera’s motion to dismiss, the preclusive effect of the nationwide settlement is another reason why Plaintiff’s claims against Caldera warrant dismissal. *See, e.g., Cooper v. Fed. Reserve Bank of Richmond*, 467 U.S. 867, 874 (1984).

one days. Doc. 27 at PageID 628. As a result, the Court ordered Plaintiff to show cause on or by December 4, 2020 as to why her claims against Caldera should not be dismissed or respond to Caldera's motion. *Id.* December 4, 2020 came and went without a response from Plaintiff.

Meanwhile, on September 11, 2020, Plaintiff and Ethicon -- but not Caldera -- submitted a stipulation allowing Plaintiff to file a second amended complaint to properly identify Ethicon. Doc. 12. Plaintiff filed a second amended complaint on the same day without first seeking leave of court. Doc. 13; *see* Fed. R. Civ. P. 15(a), (b). Ethicon moved to dismiss Plaintiff's second amended complaint pursuant to Rule 12(b)(6), arguing Plaintiff failed to state a claim under Ohio's Product Liability Act ("OPLA"). Doc. 22. On November 23, 2020, Plaintiff filed a memorandum in opposition to Ethicon's motion to dismiss and sought leave of court to file a second amended complaint. Doc. 25, 26.

Plaintiff's motion for leave, however, failed to affirmatively state -- consistent with S.D. Ohio Civ. R. 7.3(b) -- that Plaintiff's counsel solicited the consent of opposing counsel to file a second amended complaint or that such an attempt occurred. Doc. 28. Therefore, the Court denied Plaintiff's motion for leave without prejudice on November 24, 2020. *Id.* Now before the Court is Plaintiff's motion for leave to file a third amended complaint. Doc. 29.

II.

A. Caldera's Motion to Dismiss

The Court must first address Plaintiff's non-compliance with its show cause requirement. Doc. 27. Rule 41(b) provides that a court may dismiss a case for "failure of the plaintiff to prosecute or to comply with these rules or any order of [the] court." Fed. R. Civ. P. 41(b). "This measure is available to the district court as a tool to effect 'management of its docket and avoidance of unnecessary burdens on the tax-supported courts [and] opposing parties.'" *Knoll v. Am. Tel. & Tel. Co.*, 176 F.3d 359, 363 (6th Cir. 1999). A court should consider four factors when deciding

whether to dismiss a case pursuant to Rule 41(b): “(1) whether the party’s failure is due to willfulness, bad faith, or fault; (2) whether the adversary was prejudiced by the dismissed party’s conduct; (3) whether the dismissed party was warned that failure to cooperate could lead to dismissal; and (4) whether less drastic sanctions were imposed or considered before dismissal was ordered.” *Id.* “Although typically none of the factors is outcome dispositive, it is said that a case is properly dismissed by the district court where there is a clear record of delay or contumacious conduct.” *Id.* A claim may be involuntarily dismissed *sua sponte* “because of the inaction or dilatoriness of the part[y] seeking relief.” *Link v. Wabash R.R. Co.*, 370 U.S. 626, 630 (1962).

Plaintiff’s failure to prosecute her claims against Caldera renders them appropriate for Rule 41(b) dismissal. Plaintiff missed her first chance to respond to Caldera’s motion, and the Court afforded her a second opportunity to oppose the motion. Doc. 27. Plaintiff ignored both deadlines and instead only responded to Ethicon’s motion to dismiss and requested leave to file two amended complaints. Docs. 25, 26 & 29. The Court therefore construes Plaintiff’s decision not to oppose Caldera’s motion to dismiss as a tacit acknowledgement she no longer intends to pursue her claims against Caldera. Accordingly, Plaintiff’s claims against Caldera are **DISMISSED** for failure to prosecute. Because it is unnecessary to consider the merits of Caldera’s motion to dismiss (doc. 20), it is **DENIED AS MOOT**.

B. Ethicon’s Motion to Dismiss

Ethicon moves to dismiss Plaintiff’s claims for: (A) manufacturing defect, (B) design defect, (C) failure to warn, and (D) product defect in failure to conform to representations. Doc. 22-1 at PageID 600; *see also* doc. 10 at PageID 81–86.² Ethicon’s principal argument is that Plaintiff’s amended complaint should be dismissed because it is a forbidden “shotgun pleading.”

² Because Plaintiff was denied leave to file a second amended complaint (doc. 28), the Court refers to Plaintiff’s amended complaint (doc. 10) for the remainder of this Order.

Doc. 22-1 at PageID 603. Plaintiff, in her opposition memorandum, does not point to any allegation in her amended complaint tending to show that she pleads a cognizable claim for relief. Doc. 25 at PageID 622–24. Rather, she suggests she should prevail because Ethicon cannot disprove that TVT caused her harm. *Id.* Because Plaintiff’s amended complaint pleads only generalized harm and fails to offer a plausible theory of how TVT’s alleged defects caused her injury, the Court grants Ethicon’s motion to dismiss all four counts of Plaintiff’s amended complaint.

To survive a Rule 12(b)(6) motion, a plaintiff must satisfy the basic pleading requirements set forth in Rule 8(a). Under Rule 8(a)(2), a complaint must contain a “short and plain statement of the claim showing that the pleader is entitled to relief.” A complaint will not suffice if it only offers “labels and conclusions” or “a formulaic recitation of the elements of a cause of action.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)).

Instead, “a complaint must contain sufficient factual matter, accepted as true, to ‘state a claim to relief that is plausible on its face.’” *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 570). A plaintiff must plead “factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Id.* “Where a complaint pleads facts that are ‘merely consistent with’ a defendant’s liability, it ‘stops short of the line between possibility and plausibility of “entitlement to relief.”’” *Id.* (quoting *Twombly*, 550 U.S. at 557). In considering whether the facial plausibility standard is met, the court must view the complaint in the light most favorable to the plaintiff, accepting as true all allegations in the complaint and drawing all reasonable inferences in the plaintiff’s favor. *See, e.g., Kaminski v. Coulter*, 865 F.3d 339, 344 (6th Cir. 2017).

OPLA applies to product liability claims that arise in Ohio. *See* Ohio Rev. Code § 2307.71(A)(13). A manufacturer will be subject to a products liability claim only if Plaintiff establishes that the manufacturer's product was: (1) defective in manufacture or construction; (2) defective in design or formulation; (3) defective due to inadequate warning or instruction; or (4) defective due to non-conformance with the manufacturer's representations. Ohio Rev. Code §§ 2307.74–77. Each theory of liability requires Plaintiff to prove that the alleged defect was the proximate cause of his or her injury and that the manufacturer “designed, formulated, produced, constructed, created, assembled, or rebuilt” the actual product responsible for the injury. Ohio Rev. Code § 2307.73.

Even affording Plaintiff all favorable inferences, the Court cannot discern how Plaintiff was injured or what the nature of her injury was. Plaintiff's amended complaint contains a single sentence describing her alleged harm in generalized terms: after being implanted with Vertessa Lite or TVT Plaintiff experienced “significant harm, physical injury, conscious pain and suffering, and bodily impairment, including but not limited to undergoing surgical procedures, enduring hospitalization, and constantly enduring pain.” Doc. 10 at PageID 80. Vague “defendant-unlawfully-harmed-me” allegations like this are not sufficient to survive the motion to dismiss stage. *Iqbal*, 556 U.S. at 678.

It is also not clear from the face of the amended complaint whether Plaintiff is alleging that she was harmed either by Vertessa Lite, TVT, or both. *Compare* doc. 10 at PageID 79, *with id.* at PageID 68. In one paragraph of her complaint, she alleges “the Product” was implanted in her but, in another, states both Caldera TVM and TVT were implanted in her. *Compare id.* at PageID 79, *with id.* at PageID 68. In another section of her complaint, she claims both products were implanted in her for both “pelvic organ prolapse and/or stress urinary incontinence,” while in a

different paragraph she alleges TVT was implanted in her to treat only “stress urinary incontinence.” *Compare id.* at PageID 63, *with id.* at PageID 80. Failure to connect certain facts to the various causes of action alleged is the type of shotgun pleading disfavored by the federal courts. *See, e.g., Lee v. Ohio Educ. Ass’n*, 951 F.3d 386, 393 (6th Cir. 2020).

Plaintiff cannot plausibly allege proximate cause without first identifying which product caused her harm. *See, e.g., Frey v. Novartis Pharms. Corp.*, 642 F. Supp. 2d 787, 795 (S.D. Ohio 2009). Plaintiff’s amended complaint contains no specific details regarding how the particular product implanted in her was supposedly deficient and presents no allegation as to how that defect caused her harm. All she alleges is that either one or both products were implanted in her and -- at some unspecified later point in time -- she experienced pain and suffering. *See doc. 10 at PageID 80.* Such conclusory allegations do not satisfy the well-pleaded complaint rule. *See, e.g., Iqbal*, 556 U.S. at 678 (“Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice” under Rule 8). Ethicon’s motion to dismiss is, therefore, **GRANTED.**

C. Plaintiff’s Motion for Leave to File a Third Amended Complaint

Plaintiff seeks leave to file a third amended complaint to provide a more definite statement of her claim to relief. Doc. 29 at PageID 630. Ethicon argues that Plaintiff’s first, second, and proposed third amended complaints are indistinguishable and that again granting leave to file the third amend complaint would be futile. Doc. 32 at PageID 680. For that reason, Ethicon restates its motion to dismiss arguments in response to Plaintiff’s motion for leave to amend. Doc. 32 at PageID at 673.

Rule (15)(a)(2) provides that leave to amend should be given “when justice so requires.” Denial of leave is warranted when there is “undue delay in filing, lack of notice to the opposing party, bad faith by the moving party, repeated failure to cure deficiencies by previous amendments,

undue prejudice to the opposing party, and futility of amendment.” *Brumbalough v. Camelot Care Ctrs., Inc.*, 427 F.3d 996, 1001 (6th Cir. 2005).

Plaintiff’s third amended complaint does not address the deficiencies contained in the prior three pleadings. *See* doc. 29-1. Plaintiff still does not identify with any particularity which product was implanted in, or caused, her harm. *See, e.g.*, doc. 29-1 at PageID 636 (“the Product was implanted into Plaintiff”). Indeed, the allegation that she was implanted with TVT to treat stress urinary incontinence has been omitted from her third amended complaint. *Compare* doc. 10 at PageID 80, *with* doc. 29-1. The one sentence in her amended complaint that alleges she suffered generalized harm has been removed from her third amended complaint but has not been replaced with any particularized description of her alleged injury. *Compare* doc. 10 at PageID 80, *with* doc. 29-1. Plaintiff’s third amended complaint would not change the Court’s conclusion that she failed to state a plausible claim against Ethicon. Accordingly, Plaintiff’s motion for leave to amend is **DENIED**.

III.

For the foregoing reasons, the Court: (1) **GRANTS** Ethicon’s motion to dismiss; (2) **DISMISSES** Plaintiff’s claims against Caldera for failure to prosecute; (3) **DENIES AS MOOT** Caldera’s motion to dismiss; (4) **DENIES** Plaintiff’s motion for leave to file a third amended complaint; (5) **ORDERS** the Clerk to enter judgment accordingly; and (6) **TERMINATES** this case on the Court’s docket.

IT IS SO ORDERED.

Date: February 10, 2021

s/Michael J. Newman
Hon. Michael J. Newman
United States District Judge